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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,767	12/16/1999	GERALD WAYNE BOTH	50179-073	8030

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MCDERMOTT WILL & EMERY
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1632	24

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/464,767	BOTH ET AL.	
	Examiner	Art Unit	
	Scott Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48* is/are allowed.

6)☒ Claim(s) *25-34,36-47 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/02 has been entered.

A request for continued examination under 37 CFR 1.114 is not a new application. The amendment to page 1 is improper. The phrase "is a Continuation Application of ... 09/464,767, which" has been deleted.

Claims 1-24 have been cancelled. Claims 25-51 have been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 7/10/02 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

New formal drawings are required in this application because of the objections by the draftsman attached to the Office action of 7/3/01 and to incorporate the proposed correction. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The communication received on 5/16/01 remains not fully responsive to the communication mailed 2/16/01 for the reason(s) set forth on the Notice to Comply With the Sequence Rules attached to the Office action of 7/3/01.

The issue of new matter has been obviated. However, the Sequence Listing remains incomplete, as it does not contain the amino acid sequences described on page 16, line 6.

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 37 CFR 1.825. *Any* response to this Office Action which fails to meet *all* of these requirements will be considered non-responsive. The nature of the sequence disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

The Both declaration under 37 CFR 1.132 filed 7/10/02 is sufficient to overcome the objection to the specification under 35 U.S.C. 132.

Claim Objections

Claim 35 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 35 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

Claims 25-29, 31-34, 36-47 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Applicant has failed to indicate where or how the specification supports these claims. It is Applicant's burden to indicate where support is to be found in the original specification for new claims and claim limitations. See MPEP 714.02 and 2163.06(I).

Claims 25-27 recite "and which encodes a functional ovine adenovirus genome"; claims 31-

Claim 26 recites "SEQ ID NO: 13." However, there is no SEQ ID NO: 13 in the specification. It is presumed this is a typographical error, and should be --SEQ ID NO: 3--.

Claim 28 is directed to a DNA comprising the OAV287 ITR consisting of nucleotides 1-46 of SEQ ID NO: 3. Page 17, line 33 teaches that the ITRs are 40 nucleotides. It is unclear how the specification supports the ITR "consisting of nucleotides 1 through 46 of SEQ ID NO: 3."

Claims 29, 31-34, 36-47 and 49-51 recite "which comprises an/the ovine adenovirus genome" relative to a nucleotide sequence which hybridizes to SEQ ID NO: 3. This language reads on a sequence which comprises one part that hybridizes and another part which is an ovine adenoviral genome (which need not be remotely related to OAV287), as well as a sequence comprising an ovine adenoviral genome which itself hybridizes, i.e. which is structurally very similar to OAV287. The former is not supported in the specification, and this language impermissively broadens the nucleic acids disclosed in the original specification. The term "comprises" should be replaced with --is--.

In addition, claims 29,31-34, 36-47 and 49-51 do not require that the ovine adenoviral genome be functional, i.e. the viral DNA replicates in ovine cells, and comprises all cis-acting elements and encodes all products required for production of infectious virions from ovine cells. The original specification does not describe DNA, vectors, plasmids that comprise a non-functional ovine adenoviral genome. The phrase "comprises an/the ovine adenovirus genome" should be replaced with --is a functional ovine adenoviral genome--.

Claims 29, 50 and 51 further recite that the genome lacks part or all of nucleotides 28457-29014 or 28511-28699 of SEQ ID NO: 3. First of all, any insertion or deletion of nucleotides from nucleotide 1 to 28456 would create a starting sequence where its nucleotides 28457-29014 or 28511-28699 did not match or correspond to nucleotides 28457-29014 or 28511-28699 of SEQ ID NO: 3. Secondly, the specification only describes removing these sequences from OAV287 (SEQ ID NO: 3), not from some other sequence which hybridizes to SEQ ID NO: 3.

These two concepts are separately discussed in the specification, and there is no evidence of a nexus between the two. It is suggested that claim 29 be amended recite that the nucleotide sequence is identical to SEQ ID NO: 3 except for the deletion or alteration of the recited non-essential portion.

Claims 33, 34, 38-47 and 49 are directed to or require a plasmid or vector which comprises: 1) first or second nucleotide sequence; and 2) a third nucleotide sequence operatively linked to it. As the claim is written, the third nucleotide sequence must be outside of and separate from the adenoviral genome, i.e. the third sequence is not inserted into the adenoviral genome. For example, if the third sequence were inserted into the SEQ ID NO: 3, the resulting DNA would not be SEQ ID NO: 3 and the vector or plasmid would not comprise SEQ ID NO: 3. The specification discloses plasmids which contain an adenoviral genome and a marker gene as separate, adjacent parts, e.g. pOAV100, or contain an adenoviral genome wherein the bacterial vector is inserted into the adenoviral genome, e.g. pOAV287Cm. The first could meet the claim limitations, whereas the second cannot. However, the marker gene in the first is not "operatively linked" to the adenoviral genome, since these sequences are functionally independent. The specification also describes a viral vector comprising a non-adenoviral sequence, encoding a polypeptide or RNA, inserted into an ovine adenoviral genome. However, this disclosed embodiment also is not embraced by the claims, since it would not comprise the recited first or second sequence. In neither case, does the specification describe that the marker or non-

adenoviral sequence is "operatively linked" to the adenoviral genome. Furthermore, it is unclear what "operatively linked" means in this context. In order to

Claims 36-47 each recite "vector". In contrast, the specification discloses bacterial plasmids (one specific type of vector) and viral vectors, or to be more specific, ovine adenoviral vectors. There is no clear support for broadening "viral vector" to embrace other types of vector, e.g. liposomal vectors, which are not described in the specification either explicitly or implicitly.

Also, the specification does not describe "viral vectors" which comprise an adenoviral genome moiety and a non-adenoviral sequence moiety. It discloses ovine adenoviral genomes into which a non-adenoviral sequence have been inserted.

Furthermore, "viral vector" is not adequately described in the specification. The specification only describes adenoviral ovine vectors made using the OAV287 genome as the backbone. It does not describe retrovirus, herpes virus, alphavirus, AAV, etc. based vectors which comprise a functional ovine adenoviral genome, which is many cases would be physically impossible to construct, e.g. retrovirus, alphavirus, AAV, purely due to size constraints. Claims 36-47 should be amended to recite --adenoviral vector--.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application discloses and explicitly claims pOAV600 and pOAV200 that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Page 19 describes how pOAV200 and pOAV600 were made by inserting an undefined polylinker between nucleotides "22,139 and 22,130" or between nucleotides "26,645 and 26,646", respectively. First, since the linker is not identified precisely as to its structure, it cannot be reproduced. Second, it is unclear what "22,139 and 22,130" means in constructing pOAV200, the latter nucleotide appears to be a typographical error, should it be --22,140--. If so, applicant should provide evidence that such is an error, e.g. a declaration under 37 CFR 1.132. However, the lack of sequence information for the linker would prevent one from making pOAV200 and pOAV600.

Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§

1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of delivering a DNA molecule to a cultured mammalian cell, does not reasonably provide enablement for delivery to a non-mammalian cell in culture or any animal cell *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 42-44 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 41-44 and 47 are drawn to methods of transferring an exogenous DNA sequence to an unspecified target cell (claim 41), which could include any prokaryotic or eukaryotic cell, either *in vitro* or *in vivo*, e.g. Eubacteria, archaebacteria, fungi, plants, protists, fish, worms etc., or a cell in an animal (claims 42, 44 and 47) which could include anything from nematodes and other invertebrate animals to fish, mammals and other vertebrates. Mammalian adenoviruses, such as OAV287 and human adenovirus (HAV) types 2 and 5, are fairly host specific with respect to infection and propagation, although the ability to propagate in a given mammalian cell is not germane here. The ability of an adenovirus to infect a given host cell depends on the presence of membrane proteins on the target cell to which proteins exposed on the surface of the viral particle can bind. The specification shows that OAV287 can at least infect mammalian cells of non-ovine origin, but provides no working examples of or guidance for infecting target cells that are non-mammalian. While the prior art discloses that adenoviral vectors based on HAV types 2 and 5 are able to infect cells of a variety of different mammals, it is silent on whether mammalian adenoviruses are able to infect non-mammalian cells. Consequently, one skilled in the art would be unable to predict whether or not an OAV287 vector would be able to infect a non-mammalian cell, especially cells that are not from animals or are distantly related to mammals.

With respect to *in vivo* use in delivering exogenous DNA to unspecified target cells in multicellular organisms or cells in animals, the specification teaches that these vectors are primarily for use in grazing animals, presumably this means grazing mammals, for the purpose of vaccination, gene therapy, or genetic engineering to promote growth or modify production traits. The specification provides little or no guidance concerning the target animal, the route of administration, the dose and time course of treatment, and successful treatment endpoints. With the exception of antigenic proteins and peptides for vaccines, the specification provides no guidance on what types of coding sequences, antisense sequences or ribozymes should be encoded by the exogenous DNA sequence present in the viral vectors used. The specification provides no working examples of any of these uses. The specification does present evidence that the vector lacking an exogenous DNA sequence can infect and propagate in sheep.

The prior art shows that adenoviral vectors, particularly those based on HAV types 4, 5 and 7 have been used to generate full or partial protective immunity in a variety of for varying lengths of time in a variety of non-human mammals against rabies, hepatitis B, vesicular stomatitis virus, herpes simplex virus and Epstein Barr virus. See Imler (Vaccine 13(13): 1143-1151, 1995), which reviews the state of the prior art on adenoviral vector-based vaccines. Surprisingly, however, an HAV type 7 recombinant viral vector that could induce protective immunity to hepatitis B in chimpanzees, did not even result in the production of antibodies against the HBsAg expressed from the vector in humans (see Imler, page 1147, col. 2), showing some unpredictability with respect to the target mammal (note that this result was originally

published in 1992, see Ref. 54 in Imler). Also, as discussed above the specification shows that based on the dramatic structural and sequence dissimilarity between the OAV287 genome and the genomes of other well-characterized mammalian adenoviruses, OAV287 is quite a different virus than the HAV viruses on which the prior art adenoviral vaccines are based. Therefore, one cannot predict whether OAV287-based vectors would be suitable substitutes for the prior art HAV-based vectors of the prior art vaccines.

Concerning the use of the viral vectors to deliver exogenous DNA encoding products that are therapeutic, promote growth or modify production characteristics, which presumably includes polypeptides, antisense RNA and ribozymes, this art area is poorly developed and highly unpredictable. Numerous problems have been encountered which have not been shown to be overcome by routine experimentation. These include the fate of the vector (volume of distribution, rate of clearance into the tissues, rate of elimination of the vector, etc.), *in vivo* consequences of altered gene expression and protein function, the trafficking of the genetic material within the various compartments of the cell, rate of DNA degradation, amount and stability of the mRNA produced, amount and stability of the protein produced, and the compartmentalization of the protein produced. These factors differ significantly depending on the vector used, the protein produced and the effect desired or disease being treated. Orkin et al. ("Report and recommendations of the panel to assess the NIH investment in research on gene therapy", issued by the U.S. National Institutes of Health, 1995) reviews the infant state of the art of gene therapy from before the instant invention was made. The overall conclusions were: 1)

gene therapy for each disease would present its own scientific and clinical challenges; 2) no successful gene therapy protocol was known; 3) significant problems remained in all aspects of gene therapy, especially with respect to effective expression vectors; 4) the pathophysiology of diseases to be treated were poorly understood; 5) one cannot predictably extrapolate the result of one animal model, such as mouse, to treatment of a disease in a different animal, such as human; 6) assessment of known gene therapy protocols was hindered by poor gene transfer, reliance on qualitative, rather than quantitative assessments of gene transfer, lack of suitable controls and poor definition of biochemical or disease endpoints; and 7) that gene therapy has been oversold, and the impression that gene therapy is successful is mistaken (pages 1-2). It also discloses that adenoviruses are highly immunogenic, as are current vectors derived from them (page 8, para. 3), and that high immunogenicity of a viral vector may curtail long term expression and prohibit repeat administration, and that resulting counter-selection of infected cells by the immune system may contribute to lower transduction efficiencies and short-lived expression of the transgenes that has been observed (page 31, full para. 5).

In the case of antisense or ribozyme RNAs, Gewirtz et al. (Proc. Natl. Acad. Sci. USA, 93: 3161-3163, 1996) in discussing anti-mRNA methods involving antisense and ribozyme disclosed that these methods are highly variable in efficiency. The reference teaches that for a given antisense or ribozyme oligonucleotide to work in a cell, it must hybridize to an accessible RNA sequence, with sequence accessibility dependent on mRNA physical structure which is dependent upon both the primary sequence and associated proteins present in a living cell.

Structure prediction of RNA has been "fraught with difficulty". Therefore, identification of a useful antisense or ribozyme oligonucleotide is a "hit or miss process" involving many experiments in which a given oligonucleotide has no effect. (see Gewirtz et al., page 3161, col. 2-3). James (Antiviral Chemistry & Chemotherapy, 2(4): 191-214, 1991) teaches that suitable antisense molecules cannot be predicted based on the primary sequence of an mRNA target (see page 198, col. 1). Christofferson et al. (J. Med. Chem. 38(12): 2023-2037, 1995) disclosed that even after the instant invention was made, that viral delivery of ribozymes and other oligonucleotides is at an early stage of development, mostly with retroviral vectors, and that more experience with them was needed, and that the problems are those common to gene therapy (page 2029, col. 2, 1st full para.). The specification does not address solutions to any of the problems that have been plaguing the art of gene therapy, and antisense and ribozyme therapy.

Given little or no guidance on *in vivo* applications in the specification and the lack of working examples, the high unpredictability of the art of *in vivo* DNA transfer in general with respect to the disclosed gene therapy and genetic engineering uses thereof, and the excessive amount of non-routine experimentation it would require to overcome the known problems of gene therapy and the unpredictable problems associated with a new, untried vector (including using the vectors for vaccines) it would require undue experimentation to practice the invention *in vivo*.

Applicant's arguments filed 7/10/02 have been fully considered but they are not persuasive. Applicant argues that the claims do not require a therapeutic effect. However, the

only uses for the method taught in the specification are for therapy, vaccination or genetic engineering to promote growth or modify production traits. For the reasons of record, the instant specification does not enable the disclosed uses. It is not sufficient that the specification simply shows that the recombinant virus will infect a sheep, without showing that the infection produced any useful result, particularly when the prior art has demonstrated that simply getting transfection is not a reliable indicator that the transfection will produce a beneficial or useful result. It is a necessary condition, but it is not sufficient by itself.

Claims 25-27, 33, 34, 36-47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-27 recite "encodes an adenoviral genome." This is incorrect word usage, since a nucleotide sequence would not "encode" the genome, it would be the genome. Polypeptides are encoded by nucleic acids. The term "encodes" should be replaced with --is--.

Claims 33, 34, 36-40 and 49 recite "operatively linked". It is unclear what this term means in the context of these claims. The specification as filed does not use this terminology.

Claims 36, 41, 42, 45, 47 and 49 recite the limitation "the ovine adenovirus genome". There is insufficient antecedent basis for this limitation in the claim. The term should be replaced with --an ovine adenoviral genome--. This part of the rejection applies to claims dependent on these.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-28, 30-33, 36-41, 45, 46 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,020,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims either embrace the invention claimed in the '172, or the claims of the '172 recite products being instantly claimed. In either case, when the claims of the '172 patent are read in light of its specification, the claimed subject matter would anticipate the rejected claims.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG

61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
Art Unit 1632

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.